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First of 3 sheets

OCT 27 2004

K042161

510(k) SUMMARY
of
SAFETY and EFFECTIVENESS

A. General Information

1.	*Submitter's Name:*	R.J. & V.K. Bird PTY Ltd.
2.	*Address:*	25 Mills Street, Middle Park, Victoria, Australia, 3206
3.	*Telephone:*	011-61-3-9690-9898
4.	*Contact Person:*	Jonathon Bird
5.	*Date Prepared:*	July 20, 2004
6.	*Registration Number:*	3004497268

B. Device

1.	*Name:*	MDSA
2.	*Trade Name:*	Anti-Snoring / Sleep Apnea Device
3.	*Common Name:*	Anti-Snoring / Sleep Apnea Device
4.	*Classification Name:*	Device, Anti-Snoring
5.	*Product Code:*	LRK
6.	*Class:*	II
7.	*Regulation Number:*	872.5570

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C. Identification of Legally Marketed Devices

1. *Name:* TAP
2. *K Number:* K962516
3. *Date Cleared:* September 19, 1996

D. Description of the Device

The MDSA is an intraoral dental device for the treatment of snoring and sleep apnea. The MDSA is worn during sleep with the intention to reduce the incidence of snoring and obstructive sleep apnea.

The MDSA is a prescription Custom Made titratable mandibular repositioning device for the dental treatment of patients suffering snoring and obstructive sleep apnea.

Patient's dental impressions must be used to construct the device. The MDSA is a 2-part device. With an upper containing the hook component in the front that when in the patient's mouth engages a shelf in the lower.

The MDSA is supplied with an Adjuster Key, which is used to move the hook in the upper to advance the lower jaw forward and accordingly advance the mandible and tongue thereby improving patency of the airway, decrease air turbulence and aid improvement of obstructive sleep apnea.

The MDSA can be molded with commonly available materials used by Dental Laboratories either Hard Acrylic and ball clasps or Double Laminate (Hard /Soft) Functional mouthguard materials for the construction of the device.

A Bite Registration taken at the same time as the impressions facilitates the Laboratory technician correctly locating the components during construction.

Because of its unique design when incitu the patient has full lateral movement and the device can be titrated to the individual patients needs.

The advantage of the MDSA is that its construction can be easily performed by a normally qualified Laboratory Technician using standard Laboratory Equipment. This affords a saving in costs to the end user.

The MDSA components are made from Medical Grade 316 Stainless Steel. The Hook/Screw component is welded into its outer housing to ensure security during use.

E. Intended Use Statement

The MDSA is an intraoral device (mandibular repositioning) for the treatment of snoring and sleep apnea. The device is worn during sleep with the intention to reduce the incidence of snoring and obstructive sleep apnea.

F. Technological Characteristics Summary

Similarities between both devices are the following:

- Indications for Use
- Single Patient
- Multi-Use
- Prescription Device
- Non-Sterile
- Custom Fabricated (Fit)
- Adjustable
- Environment – Home/Sleep Laboratories
- Components
- Two Trays (Upper and Lower)
- Materials – Stainless Steel, Vinyl, Acrylic
- Removable

Differences are the MDSA has a separate Adjuster Key versus a winder. The MDSA has a hook in the upper that engages a shelf in the lower tray rather than a lingual bar, which overcomes impedance of the tongue space when the mandible is advanced forward.

The general differences are minor and do *not* raise safety concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 2004

Mr. Jonathon Bird
Export Development Manager
RJ & VK Bird Pty Limited
25 Mills Street
Middle Park, Victoria,
AUSTRALIA 3206

Re: K042161
Trade/Device Name: Anti® Snoring/Sleep Apnea Device
Regulation Number: 872.5570
Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for Snoring and Obstructive Sleep Apnea
Regulatory Class: II
Product Code: LRK
Dated: July 20, 2004
Received: August 10, 2004

Dear Mr. Bird:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K042161

Indications for Use

510(k) Number: K042161

Device Name: MDSA®

Indications for Use:

- Prescription Device
- Custom-Made
- Mandibular Repositioning Device
- Reduce Snoring
- Treat Mild to Moderate Obstructive Sleep Apnea
- Single Patient / Multi-Use
- Not for Use in Persons Younger than 18 Years of Age
- Home or Sleep Laboratory Environment

Prescription Use X AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K042161